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UTILITY PATENT APPLICATION TRANSMITTAL
(Small Entity)

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Docket No. 43169.62.1
Total Pages in this Submission 41

TO THE ASSISTANT COMMISSIONER FOR PATENTS
Box Patent Application
Washington, D.C. 20231

Transmitted herewith for filing under 35 U.S.C. 111(a) and 37 C.F.R. 1.53(b) is a new utility patent application for an invention entitled:

ELECTRICAL CARDIAC OUTPUT FORCER

and invented by:

Kai Kroll
Mark W. Kroll

If a CONTINUATION APPLICATION, *check appropriate box and supply the requisite information:*

☒ **Continuation** ☐ **Divisional** ☐ **Continuation-in-part (CIP)** of prior application No.: **SEE ATTACHED**

Which is a:

☐ **Continuation** ☐ **Divisional** ☐ **Continuation-in-part (CIP)** of prior application No.: _____

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Enclosed are:

Application Elements

1. ☐ Filing fee as calculated and transmitted as described below

2. ☒ Specification having **23** pages and including the following:

   a. ☒ Descriptive Title of the Invention
   b. ☒ Cross References to Related Applications *(if applicable)*
   c. ☐ Statement Regarding Federally-sponsored Research/Development *(if applicable)*
   d. ☐ Reference to Microfiche Appendix *(if applicable)*
   e. ☒ Background of the Invention
   f. ☒ Brief Summary of the Invention
   g. ☒ Brief Description of the Drawings *(if drawings filed)*
   h. ☒ Detailed Description
   i. ☒ Claim(s) as Classified Below
   j. ☒ Abstract of the Disclosure

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Application Elements (Continued)

3. ☒ Drawing(s) *(when necessary as prescribed by 35 USC 113)*

   a. ☐ Formal b. ☒ Informal Number of Sheets **11**

4. ☒ Oath or Declaration

   a. ☐ Newly executed *(original or copy)* ☐ Unexecuted

   b. ☒ Copy from a prior application (37 CFR 1.63(d)) *(for continuation/divisional application only)*

   c. ☐ With Power of Attorney ☐ Without Power of Attorney

   d. ☐ *DELETION OF INVENTOR(S)*
   Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. 1.63(d)(2) and 1.33(b).

5. ☒ Incorporation By Reference *(usable if Box 4b is checked)*
The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

6. ☐ Computer Program in Microfiche

7. ☐ Genetic Sequence Submission *(if applicable, all must be included)*

   a. ☐ Paper Copy

   b. ☐ Computer Readable Copy

   c. ☐ Statement Verifying Identical Paper and Computer Readable Copy

Accompanying Application Parts

8. ☐ Assignment Papers *(cover sheet & documents)*

9. ☐ 37 CFR 3.73(b) Statement *(when there is an assignee)*

10. ☐ English Translation Document *(if applicable)*

11. ☐ Information Disclosure Statement/PTO-1449 ☐ Copies of IDS Citations

12. ☐ Preliminary Amendment

13. ☒ Acknowledgment postcard

14. ☒ Certificate of Mailing

    ☐ First Class ☒ Express Mail *(Specify Label No.):* **EL486400803US**

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Accompanying Application Parts (Continued)

15. ☐ Certified Copy of Priority Document(s) *(if foreign priority is claimed)*

16. ☒ Small Entity Statement(s) - Specify Number of Statements Submitted: **established May 31, 1994**

17. ☐ Additional Enclosures *(please identify below):*

Fee Calculation and Transmittal

CLAIMS AS FILED

For	#Filed	#Allowed	#Extra	Rate	Fee
Total Claims	25	- 20 =	5	x $9.00	$45.00
Indep. Claims	3	- 3 =	0	x $40.00	$0.00
Multiple Dependent Claims (check if applicable) ☐					$0.00
				BASIC FEE	$355.00
OTHER FEE ***(specify purpose)***					$0.00
				TOTAL FILING FEE	$400.00

☐ A check in the amount of to cover the filing fee is enclosed.

☐ The Commissioner is hereby authorized to charge and credit Deposit Account No. as described below. A duplicate copy of this sheet is enclosed.

- ☐ Charge the amount of as filing fee.
- ☐ Credit any overpayment.
- ☐ Charge any additional filing fees required under 37 C.F.R. 1.16 and 1.17.
- ☐ Charge the issue fee set in 37 C.F.R. 1.18 at the mailing of the Notice of Allowance, pursuant to 37 C.F.R. 1.311(b).

Dated: 30 October 2000

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09/693551
10/20/00

Attorney Docket No. 43169.62.1

Attachment to Utility Patent Application Transmittal:

If a continuation application, check appropriate box and supply the requisite information:

X Continuation of prior application no. 09/139,822 filed August 25, 1998;

Which is a:

X Continuation of prior application no. 08/754,712 filed December 6, 1996;

Which is a:

X Continuation of prior application no. 08/543,001 filed October 13, 1995, now abandoned;

Which is a:

X FWC of application no. 08/251,349 filed May 31, 1994 now abandoned.

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ELECTRICAL CARDIAC OUTPUT FORCER

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention relates to the field of therapies for cardiac arrhythmias, and more particularly, to a method and an apparatus for forcing cardiac output by delivering a pulsatile electrical field to the heart during fibrillation or a hemodynamically compromising tachycardia.

2. Background Information

Approximately 400,000 Americans succumb to ventricular fibrillation each year. It is known that ventricular fibrillation, a usually fatal heart arrhythmia, can only be terminated by the application of an electrical shock delivered to the heart. This is through electrodes applied to the chest connected to an external defibrillator or electrodes implanted within the body connected to an implantable cardioverter defibrillator (ICD). Paramedics cannot usually respond rapidly enough with their external defibrillators to restore life. New methods of dealing with this problem include less expensive external defibrillators (and thus more readily available) and smaller implantable defibrillators. Since the first use on humans of a completely implantable cardiac defibrillator in 1980, research has focused on making them continually smaller and more efficient by reducing the defibrillation threshold energy level. The goal has been to reduce the size of the implantable device so that it could be implanted prophylactically, i.e., in high risk patients before an episode of ventricular fibrillation.

An ICD includes an electrical pulse generator and an arrhythmia detection circuit coupled to the heart by a series of two or more electrodes implanted in the body. A battery power supply, and one or more charge storage capacitors are used for delivering defibrillation shocks in the form of electrical current pulses to the heart. These devices try to restore

normal rhythm from the fibrillation. While it works well at restoring normal function, the ICD is large in size and not practical for a truly prophylactic device. A small device capable of maintaining minimal cardiac output, in high risk patients, prior to admission into an emergency room is needed.

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In addition, external defibrillators are limited in their performance. The typical paramedic defibrillation may be delayed by 10 minutes. At this time defibrillation may be irrelevant since the rhythm is often advanced to asystole. In asystole, there is little or no electrical activity and certainly no cardiac pumping.

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There is a need for a new method and apparatus for dealing with ventricular fibrillation. The defibrillation approach does not work satisfactorily. External devices are too slow in arrival and implantable defibrillators are excessively large (and expensive) for prophylactic use.

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SUMMARY OF THE INVENTION

The invention provides an electrical method of stimulating cardiac cells causing contraction to force hemodynamic output during fibrillation, hemodynamically compromising tachycardia, or asystole. Forcing fields are applied to the heart to give cardiac output on an emergency basis until the arrhythmia ceases or other intervention takes place. The device is usable as a stand alone external or internal device or as a backup to an ICD, atrial defibrillator, or an anti-tachycardia pacemaker.

The goal of the invention is maintaining some cardiac output and not necessarily defibrillation. The method is referred to as Electrical Cardiac Output Forcing and the apparatus is the Electrical Cardiac Output Forcer (ECOF).

In the implantable embodiment, a forcing field is generated by applying approximately 50 volts to the heart at a rate of approximately 100 - 180 beats per minute. These fields are applied after detection of an arrhythmia and maintained for up to several hours. This will generate a cardiac output which is a fraction of the normal maximum capacity. The heart has a 4 or 5 times reserve capacity so a fraction of normal pumping activity will maintain life and consciousness.

The implantable embodiment is implanted in high risk patients who have never had fibrillation. If they do fibrillate, the ECOF device forces a cardiac output for a period of up to several hours, thus giving the patient enough time to get to a hospital. That patient would then be a candidate for an implantable cardioverter defibrillator (ICD). The ECOF differs from the ICD in that it is primarily intended for a single usage in forcing cardiac output over a period of hours, while the ICD is designed to furnish hundreds of defibrillation shocks over a period of years.

Insofar as is known, no prior attempts have been made at forcing pulses during any type of fibrillation. Some workers in the field have experimented for research purposes with local pacing during fibrillation. For example, Kirchhof did local pacing during atrial fibrillation in dog hearts (Circulation 1993; 88: 736 - 749). He used 0.5 mm diameter electrodes and pacing stimuli. As expected, small areas around the heart were captured but no pumping action was expected or detected. Similar results have been obtained in the ventricle by KenKnight (Journal of the American College of Cardiology 1994; 283A).

Various researchers have tried multiple pulse defibrillation without success in reducing the energy thresholds, for example, Schuder (Cardiovascular Research; 1970, 4, 497-501), Kugelberg (Medical & Biological Engineering; 1968, 6, 167-169 and Acta Chirurgica Scandinavia; 1967, 372), Resnekov (Cardiovascular Research; 1968, 2, 261-264), and Geddes (Journal of Applied Physiology; 1973, 34, 8-11).

More recently, Sweeney (U.S. Patent No. 4,996,984) has experimented with multiple (primarily dual) shocks of timing calculated from the fibrillation rate. None of these approaches has been able to significantly reduce voltages from conventional defibrillation shocks. Importantly, none of these approaches anticipated the idea that the individual pulses might force cardiac output or could sustain life indefinitely.

Some have considered the use of smaller pulses, before the shock, to reduce the energy required for a defibrillation shock (Kroll, European Application No. 540266), but never anticipated eliminating the defibrillation shock itself or anticipated that the pulses themselves could maintain cardiac output. Some have suggested using higher voltage pulses to terminate ventricular tachycardias, but no suggestion was made of an application

with fibrillation or of obtaining cardiac output (Kroll WO 93/19809) and Duffin (WO 93/06886).

The benefits of this invention will become clear from the following description by reference to the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a block diagram illustrating a system constructed in accordance with the principles of the present invention.

Figure 2a shows the connection of an implantable embodiment of the device to the heart in an epicardial patch configuration.

Figure 2b shows the connection of an implantable embodiment of the device to the heart using an endocardial lead system and the device housing as an electrode.

Figure 3 shows the connection of an external embodiment of the invention.

Figure 4 is a diagram showing a representative pulsatile electrical signal.

Figure 5 is a flowchart illustrating one embodiment of the method of the invention.

Figure 6 is a diagram showing the expected effect of a 50 V pulse on the heart during diastole.

Figure 7 is a diagram showing the expected effect of a 50 V pulse on the heart during systole.

Figure 8 is a diagram showing the expected effect of a 50 V pulse on the heart during fibrillation.

Figures 9a and 9b show various waveforms useful for the electrical cardiac output forcing method and apparatus.

Figure 10 shows the device used as a backup to an atrial defibrillator.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention will now be described more fully hereinafter with reference to the accompanying drawings, in which preferred embodiments of the invention are shown. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein. Rather, applicants provide these embodiments so that this disclosure will be thorough and complete, and will convey the scope of the invention to those skilled in the art.

Figure 1 is a block diagram illustrating a system 10 constructed in accordance with the principles of the present invention. The device circuitry is connected to the heart 40 via a series of leads; output lead 32, pressure sense lead 34, and ECG sense lead 36. The electronic circuit includes a conventional ECG amplifier 30 for amplifying cardiac signals. The amplified cardiac signals are analyzed by a conventional arrhythmia detector 20 which determines if an arrhythmia is present. The arrhythmia detector 20 may be one of several types well known to those skilled in the art and is preferably able to distinguish between different types of arrhythmias. For example; fibrillation, tachycardia or asystole. The circuit also contains an optional pressure sensing section 28 which amplifies and conditions a signal from an optional pressure sensor from within the heart or artery. The output of the pressure sense circuit 28 is fed to a cardiac output detection circuit 18 which analyzes the data and determines an estimate of the cardiac output. Data from the arrhythmia detector circuit 20 and the cardiac output detection circuit 18 is fed to the microprocessor 16. The microprocessor 16 determines if Electrical Cardiac Output Forcing (ECOF) is appropriate. If forcing is indicated, the microprocessor 16 prompts the output control 22 to charge a capacitor within the output circuit 26 via the capacitor charger 24. The output control 22 directs the output circuitry 26 to deliver the pulses to the heart 40 via the output leads 32.

The microprocessor 16 may communicate with external sources via a telemetry circuit 14 within the device 10. The power for the device 10 is supplied by an internal battery 12.

Figure 2a is a diagram showing the connection of an implantable embodiment of the device 130 to the heart 40 in an epicardial patch configuration. In this thoracotomy configuration, current passes through an output lead pair 32 to electrode patches 42 which direct the current through the heart 40. There is an optional pressure sense lead 34 which passes the signal from an optional pressure transducer 46 which lies in the heart 40. The ECG is monitored by sense electrodes 44 and passed to the device 130 by a lead 36. The area of the electrodes 42 is at least 0.5 cm^2. The size of the electrode is greater than that of a pacing lead and no more than that of a defibrillation electrode or between approximately 0.5 cm^2 and 20 cm^2 each.

Figure 2b shows a non-thoracotomy system embodiment of the invention. In this system, the current passes from a coil electrode 52 in the heart 40 to the housing of the device 140. An endocardial lead 50 combines the ECG sensing lead and the pulse output lead. The ECG is monitored by sense electrodes 44 in the heart 40 and passes through the endocardial lead 50. There is an optional pressure transducer 46 in the heart 40 which passes a signal to the device 140 via optional lead 34.

Figure 3 shows an external embodiment of the invention. External patch electrodes 54 are placed on the chest to deliver current to the heart 40 through output lead 32. The ECG is monitored by surface electrodes 56 and passed to the device 150 by a lead 36. Alternately, the ECG could be monitored by the external patch electrodes 54. An optional pressure sensor 46 passes a pressure signal via an optional pressure sense lead 34. This embodiment could be used as a substitute (due to its small size) for an external defibrillator and keep a patient alive until arrival at a hospital. Also, the system could precede the

external defibrillator by generating output in patients in asystole until blood flow and rhythm are restored.

A series of forcing pulses 60 are shown in figure 4. The pulses are approximately 50 V in amplitude with a spacing of approximately 500 ms. The 50 V and the 500 ms pulse spacing are chosen as illustrative for an implantable embodiment. The forcing pulse interval is chosen to maximize cardiac output within the limits of device circuitry and the response of the heart muscle. An interval of 500 ms corresponds to a heart rate of 120 beats per minute. This will produce a greater output than a typical resting rate of 60 beats per minute. However, a rate of 240 beats per minute would produce a lower output due to mechanical limitations of the heart. Thus a practical range is 60 to 200 beats per minute is appropriate. The pulses could also be timed to coincide with the natural pumping of the atria, thus improving overall cardiac output.

The higher the voltage, the higher the forcing fields, and therefore a greater number of heart cells contracting producing greater cardiac output. However, the higher voltage produces greater patient discomfort and extraneous muscle twitching.

Implantable batteries are also limited to a certain power output and energy storage. If an output pulse is 50 V and the electrode impedance is 50 Ω, the power during the pulse is $P = V^2/R = 50V*50V/50\Omega = 50$ W. If the pulse has a duration of 2 ms then the energy per pulse is 0.1 J. If two pulses are delivered every second, the charger must be capable of delivering 0.2 J per second which is 200 mW. This is well within the limits of an implantable battery. An implantable battery can typically deliver 5 W of power. However, 200 V pulses at 3 per second would require 4.8 W which is near the limit of the battery and charging circuitry. A typical implantable battery energy capacity is 10,000 J. Delivering forcing pulses at a rate of 4.8 W would deplete the battery in only 35 minutes

(10,000J/4.8W = 2083 seconds). Thirty five minutes may not be enough time to transport the patient to a hospital. Therefore 200 V represents the highest practical voltage for continuous operation in an implantable embodiment, although voltages of up to 350 V could be used for short periods and adjusted down when hemodynamic output is verified. A practical lower limit is about 10 V. During normal sinus rhythm, 10 V delivered through the patches would pace. However, during fibrillation the 10 V could not pace and only cells very near the electrodes would be captured. This would be insufficient for forcing cardiac output.

These calculations also suggest other differences between an implantable ECOF and an ICD. With a battery storing 10,000 J and an ECOF pulse having 0.1 J, this ECOF would be capable of delivering 100,000 pulses. An ICD can only deliver 200 - 400 shocks of about 30 J. The ECOF is also very different from an implantable pacemaker which typically delivers 150,000,000 pacing pulses (5 years at 60 BPM) each of about 0.00005 J.

For an external ECOF the calculations are similar, but scaled up. The typical ECOF pulse would have a voltage of 100 V with a range of 25 - 500 V. With electrode impedances of 50 Ω the power during the pulse is $P = V^2/R = 100V*100V/50\Omega = 200$ W with a range of 12.5 - 5,000 W. If the pulse has a duration of 2 - 5 ms, then the energy per pulse is 0.02 - 25 J. This is much less than the American Heart Association recommended output of 360 J for an external defibrillator.

This is also different from an external transthoracic pacemaker. These devices are rated by current and typically have an output range of 30 - 140 mA. Most patients are paced by pulses of 40 - 70 mA of current. An example of a modern external external thoracic pacemaker is given by Freeman in application WO 93/01861. Assuming an electrical impedance of 50Ω and the ECOF voltage range of 25 - 500 V, then the ECOF current range

would be 500 mA to 10 A. Since electrode impedance increases with lower voltage, the 25 V ECOF pulse would probably see an impedance of 100Ω thereby giving a lower current of 250 mA.

Figure 5 is a flowchart illustrating the method of the invention, which is provided for purposes of illustration only. One skilled in the art will recognize from the discussion that alternative embodiments may be employed without departing from the principles of the invention. The flow diagram shown in Figure 5 represents a method of automatically treating a heart which is in fibrillation, tachycardia, or asystole and thereby pumping inefficiently or not at all. Electrodes are attached 69 and diagnoses the presence of an arrhythmia 70. A series of cardiac output forcing electric pulses 72 is automatically delivered. It should be understood that the therapy 72 may be delivered for any output compromising cardiac arrhythmia. After delivery of 10 forcing pulses (at a rate of 60 - 200 BPM) in the first block 72, the status of the heart is determined 74. If an arrhythmia is still present and there exists low pressure within the heart, more forcing pulses are delivered 78. If the heart is pumping at a safe level, the therapy ceases and exits 76. Note that this means that the ECOF successfully defibrillated the patient's heart even though this is not a primary goal of the system. This could be tested in patients who were scheduled to receive an ICD, in a hospital setting. Those patients who are defibrillated by ECOF pulse therapy could then receive the ECOF instead of the larger ICD. After the therapy 78 has been delivered, the pressure and ECG is again monitored 74. If the therapy 78 is successful, it ceases and exits 76. If the therapy 78 is unsuccessful in producing a safe level of pumping efficiency, the method proceeds to a continuous cardiac assist mode 80. The therapy may only be stopped by an external command, for example, a telemetry signal or a magnet which is applied to the chest activating a magnetic reed switch 82 which terminates the therapy and exits 76. To minimize patient discomfort and maximize battery life, the forcing voltage could be adjusted down when sufficient pressure signals or adequate flow

measured by other means were detected, for example, the pressure sense transducer could be replaced by an oxygen detector or a doppler flow measuring device. The pulse rate could also be adjusted to maximize output.

Figure 6 is a diagram showing the effect of a 50 V forcing pulse on the heart 40 during electrical diastole (cells at rest). The current is passed through the heart 40 by the electrodes 42. Approximately 60% of cardiac cells 90 would be captured by a 50 V pulse if the cells were in diastole. The captured cells 90 mostly lie in the direct path between the electrodes 42 and near the electrodes 42 where the field strengths are highest. Of course, over a time period of about 100 ms these directly captured cells then propagate an activation wavefront to stimulate the rest of the heart. This so called far-field pacing is irrelevant here as the hearts, of interest, are in fibrillation and not in diastole.

Figure 7 is a diagram showing the effect of a 50 V forcing pulse on the heart during electrical systole (cells already stimulated). The current is passed through the heart 40 by the electrodes 42. Approximately 20% of cardiac cells 100 would be captured by a 50 V pulse if the cells were in systole. The captured cells 100 are nearest each electrode 42 where the field strengths are highest. Capture in systolic cells means that their activation potential is extended. This capture requires significantly higher fields (10 V/cm) than those required for diastolic cell capture (1 V/cm).

Figure 8 is a diagram showing the effect of a 50 V forcing pulse on the heart during fibrillation. During fibrillation there are always cells in systole and diastole simultaneously. But, the vast majority are in systole. This diagram assumes 50% of the cells are in diastole which applies only after several capturing pulses. The current is passed through the heart 40 by the electrodes 42. 100% of the cells 110 nearest the electrodes 42 would be captured due to the high field strength. As shown in figure 7, even systolic cells are captured by

high field strengths. 50% of the cells 112 in the direct path between the electrodes 42 would be captured if it is assumed that 50% of all cells are in diastole. If roughly 60% of cardiac cells are captured by a 50 V pulse when the cells are in diastole, and 20% are captured when in systole, and if 50% are in systole and 50% in diastole, 40% would be captured during fibrillation. This calculation is shown in the following table. The last two columns give the mechanical action resulting and the contribution to forcing a cardiac output.

Considering the cardiac cells that are originally in diastole, (rows A & B) in the table below, the A row represents the diastolic cells that are not captured by the forcing pulse. If 50% of the heart's cells are in diastole and 40% of those are not captured that is 20% of the total cells. These cells will, however, shortly contract on their own (from previous wavefronts or new ones) providing a positive gain in mechanical action and therefore cardiac output. The B row corresponds to the diastolic cells that are captured. If 60% of the diastolic cells (50% of total) contract due to the forcing field this is 30% of the total heart cells. These cells provide the biggest gain in mechanical action and cardiac output. Next considering the activity of the systolic cells (rows C & D), if 50% of the heart's cells are in systole and 80% of those are not captured (row C), that is 40% of the heart's cells. These cells soon relax and negate a portion of the cardiac output. The systolic cells that are captured (row D) are 10% of the heart's cells (20% of 50%). These cells will hold their contraction and be neutral to cardiac output. The net result is a gain in contraction which forces cardiac output.

Original status of the cells	Percentage of the cardiac cells	Status of the cardiac cells	Percentage of the original status	Percentage of the total cells	Mechanical Action	Forcing Cardiac Output Effect
(A) Diastolic	50%	Diastolic non-captured	40% of 50%	20%	will start to contract on own	positive (+)
(B) Diastolic		Diastolic captured	60% of 50%	30%	contract	positive (++)
(C) Systolic	50%	Systolic non-captured	80% of 50%	40%	will start to relax on own	negative (-)
(D) Systolic		Systolic captured	20% of 50%	10%	hold	neutral (0)
Total	100%		100%	100%	more contraction	positive (++)

The net result over a 200 ms mechanical response is given in the next table. The major contribution is in row (B) from the captured diastolic cells contracting.

Row	Status of the Cardiac Cells	Change in Output	Description of Activity
A	Diastolic non-captured	+5%	Positive. Some cells will begin to contract on their own.
B	Diastolic captured	+30%	Positive. Cells contract due to forcing field.
C	Systolic non-captured	-5%	Negative. Some cells will begin to relax on their own.
D	Systolic captured	0%	Neutral. Cells hold contraction due to forcing field.
Net Gain		+30%	A net gain in cardiac output due to forcing fields.

The 30% net pumping action should be sufficient to maintain survival and consciousness, because the heart has a 4 - 5 times reserve capacity.

Figure 9 depicts examples of waveforms designed to minimize the twitching of the chest muscles which can be very uncomfortable to the patient. In figure 9a is seen a low harmonic pulse waveform 120 which has a very gradual "foot" 122 and a gradual peak 124. Such a pulse has less high frequency energy components and thus is less likely to stimulate the skeletal muscle.

Figure 9b shows a technique of going to the opposite extreme. Here, each compound forcing pulse 126 is actually composed of 50 very short spikes 128 each of which is 20 μs in width with a 20 μs spacing. The heart will tend to average out these thin pulses and "see" a 2 ms wide forcing pulse. The skeletal muscle, however, is not efficiently

stimulated by these extremely narrow pulses. The skeletal muscle will not average out this signal either. This approach could help minimize skeletal muscle twitching and discomfort.

An alternative system would be to charge the capacitor to 300 V for the first pulse to capture many cells therefore putting those cells into diastole after a delay of 100 - 200 ms. At this point the voltage could be lowered to 100 V and delivered every 100 ms. A 3 watt DC-DC converter with a 67% efficiency could provide 100 ms interval forcing pulses assuming a 50 Ω resistance and 1 ms pulse (0.2 J). This rate is too fast for forcing cardiac output due to mechanical limitations, but is very effective for electrical capture. After sufficient capture, the rate of forcing pulses could be slowed down to 100 - 170 beats per minute for optimum cardiac output.

The Electrical Cardiac Output Forcing device (ECOF) could also be used to help patients with atrial fibrillation. As an alternative embodiment to the ventricular placement of Figure 2b, the electrode coil 52 and sensing electrodes 44 could be placed in the atrium. The device could then function to force atrial output. Even though atrial fibrillation is not instantly fatal like ventricular fibrillation is, clots can build up in the atria which can eventually lead to strokes. Cardiac output forcing of the atria on a daily basis may limit this problem. It is also possible that after a number of forcing pulses the atria would return to a normal rhythm. There is however, no urgency as is the case with ventricular fibrillation.

A second use of this invention for atrial defibrillation is shown in Figure 10. As before in Figure 2b, the ECOF 160 is shown connected to the heart 40 via endocardial lead 50. Again forcing coil electrode 52 and sensing electrodes 44 are in the right ventricle. In addition a large atrial coil electrode 130 and atrial sensing electrodes 132 are in the right atrium. These would be used for conventional atrial defibrillation. One of the big concerns

with atrial defibrillation is that in a few cases, an atrial defibrillation shock causes ventricular fibrillation. If this happens, the patient dies within minutes. With the ECOF approach, for the left ventricle, one could maintain output in the patient for several hours and thus have enough time for transport to a hospital or external defibrillation. Thus the ECOF approach in the ventricle could provide a safety backup to atrial defibrillation.

Many cardiac patients have no known risk of ventricular fibrillation, but suffer regularly from ventricular tachycardia. Accordingly, these people can be treated with anti-tachycardia pacing (ATP). Unfortunately, occasionally ATP will cause a ventricular fibrillation. Then a large defibrillation shock must be applied. Thus it is not considered safe to implant a pure ATP device and these patients instead receive a full size ICD. The ECOF approach also serves as a safety backup and thus allow the implantation of true ATP devices. The system is depicted in Figure 2b, although the pressure sensor 46 would typically not be needed.

Low energy cardioverters can also be used to treat ventricular tachycardias. These devices are also not considered safe as stand alone devices due to the fact that they may not terminate the rhythm or that they may cause fibrillation. The ECOF method also could is used as a safety backup thus allowing the implantation of cardioverters without defibrillation capabilities. Such a system is shown in Figure 2b.

It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. For example, while most of the discussion is in the context of an implantable device, the concepts of the invention are also applicable to external delivery systems. It is intended that the following claims define the scope of the invention and that structures and methods within the scope of these claims and their equivalents be covered thereby.

I claim:

1. A method for electrically forcing cardiac output during an arrhythmia in a patient, comprising the steps of:

(a) attaching electrodes to the patient's chest;

(b) confirming the presence of an arrhythmia; and

(c) delivering electrical current pulses through the patient's chest by means of said electrodes said electrical current pulses being delivered at a rate between 60 and 200 beats per minute and said electrical current pulses having a sufficient strength to directly force contraction in the patient's heart, whereby the method provides a level of cardiac output sufficient to maintain life.

2. The method of claim 1, further comprising the steps of reassessing the presence of an arrhythmia at predetermined intervals and terminating said delivery of electrical forcing pulses if the arrhythmia is no longer present.

3. The method of claim 1, in which the arrhythmia is asystole.

4. The method of claim 1, in which the arrhythmia is a tachycardia.

5. The method of claim 1, in which the arrhythmia is fibrillation.

6. The method of claim 1, in which each electrical current pulse has a maximum energy of less than 360 joules.

7. The method of claim 1, further comprising the steps of monitoring cardiac output and adjusting electrical current pulse amplitude to maintain a predetermined level of cardiac output, thereby conserving electrical energy.

8. The method of claim 7, in which cardiac output is monitored by external blood pressure monitoring means.

9. The method of claim 1, in which each electrical current pulse is shaped with rounded edges thereby minimizing patient discomfort and chest twitching.

10. The method of claim 1 in which each electrical current pulse is formed of a train of at least 10 narrow pulses thereby minimizing patient discomfort and chest twitching.

11. A device, for implantation in the human body, for maintaining cardiac output using forcing fields, comprising:

(a) battery power supply means;

b) arrhythmia detection means connected to said battery power supply means; and

(c) output control means connected to said arrhythmia detection means and connected to said battery power supply means for delivering multiple electrical current pulses to the human heart after the detection of an arrhythmia, wherein the maximum voltage of said electrical current pulses is less than 375 volts, contraction in the patient's heart is directly forced and a level of cardiac output sufficient to maintain life is provided.

12. The device of claim 11, in which said electrical current pulses are delivered at a rate between 60 and 200 beats per minute.

13. The device of claim 11, in which said battery power supply means has sufficient capacity to deliver said electrical current pulses for at least 1 hour.

14. The device of claim 11, in which the arrhythmia is a tachycardia.

15. The device of claim 11, in which the arrhythmia is fibrillation.

16. The device of claim 11, further comprising blood pressure monitoring means.

17. The device of claim 11, further comprising oxygen content of the blood monitoring means.

18. The device of claim 16, in which said blood pressure monitoring means monitors cardiac output and said electrical current pulse amplitude is adjusted by said output control means to maintain a predetermined level of cardiac output thereby conserving electrical energy.

19. The device of claim 11, in which each electrical current pulse is shaped with rounded edges, thereby minimizing patient discomfort and chest twitching.

20. The device of claim 11, in which each electrical current pulse is formed of a train of at least 10 narrow pulses, thereby minimizing patient discomfort and chest twitching.

21. The device of claim 11 in which said arrhythmia detection means reassesses the presence of arrhythmia at predetermined intervals and said electrical current pulses are stopped by said output control means if the arrhythmia is no longer present.

22. The device of claim 11, further comprising means to perform conventional anti-tachycardia pacing thereby providing the electrically forced emergency cardiac output in the event of anti-tachycardia pacing causing a ventricular fibrillation.

23. The device of claim 11, further comprising means to perform tachycardia cardioversion, thereby providing the electrically forced emergency cardiac output in the event of cardioversion causing a ventricular fibrillation.

24. The device of claim 11, further comprising means to perform atrial defibrillation, thereby providing the electrically forced emergency cardiac output in the event of atrial defibrillation causing a ventricular fibrillation.

25. A method for electrically forcing cardiac output during an arrhythmia, comprising the steps of:

(a) detecting the presence of the arrhythmia in a human heart; and

(b) delivering electrical current pulses through said human heart; wherein said electrical current pulses are delivered at a rate of between 60 and 200 beats per minute, and wherein said predetermined electrical current pulses are strong enough to directly force contraction in parts of the patient's heart; thereby providing a level of cardiac output sufficient to maintain life in spite of the arrhythmia without necessarily defibrillating the patient.

ABSTRACT OF THE INVENTION

An electrical method and apparatus for stimulating cardiac cells causing contraction to force hemodynamic output during fibrillation, hemodynamically compromising tachycardia, or asystole. Forcing fields are applied to the heart to give cardiac output on an emergency basis until the arrhythmia ceases or other intervention takes place. The device is used as a stand alone external or internal device, or as a backup to an ICD, atrial defibrillator, or an anti-tachycardia pacemaker. The method and apparatus maintain some cardiac output and not necessarily defibrillation.

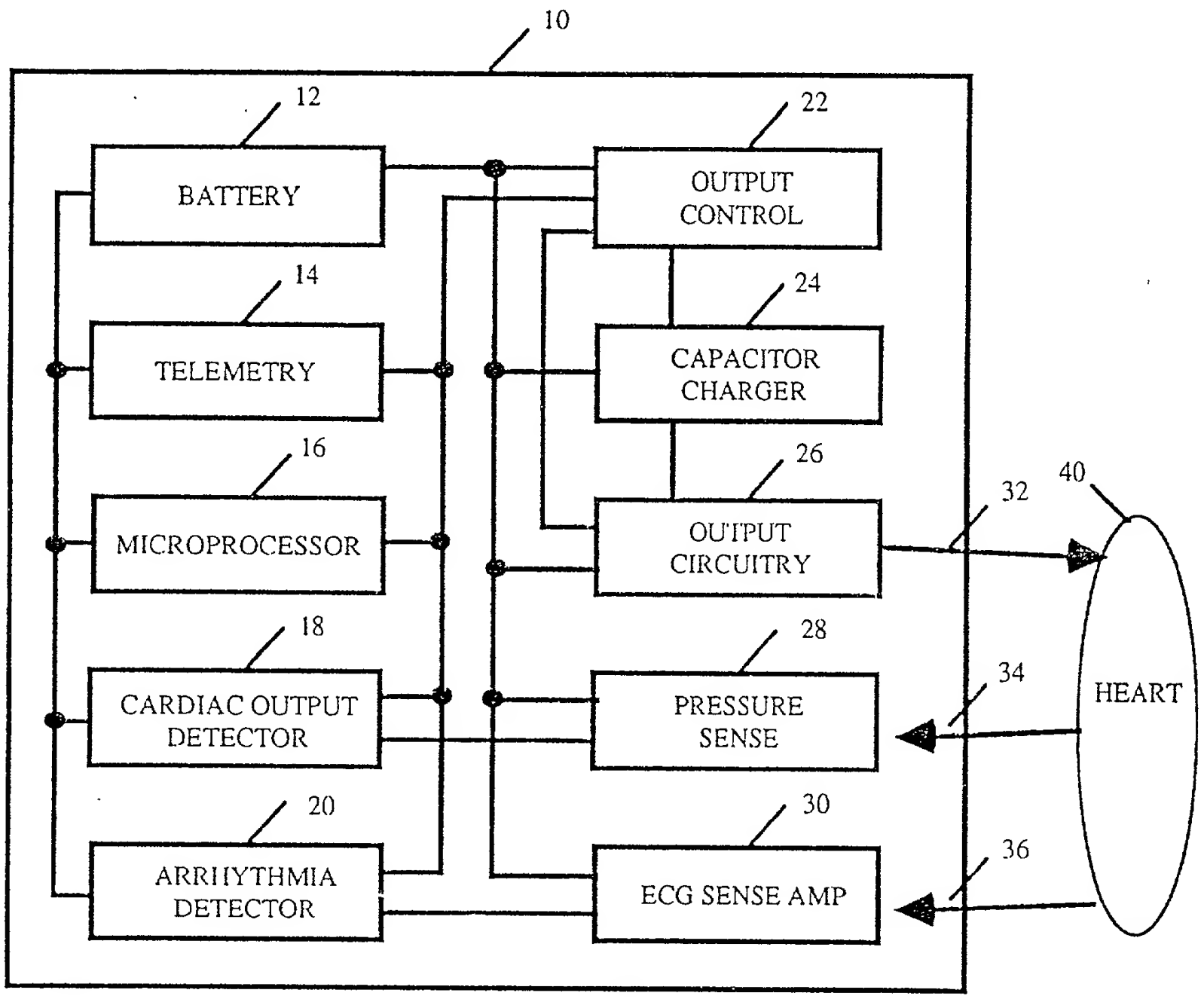
10
12
BATTERY
14
TELEMETRY
16
MICROPROCESSOR
18
CARDIAC OUTPUT DETECTOR
20
ARRHYTHMIA DETECTOR
22
OUTPUT CONTROL
24
CAPACITOR CHARGER
26
OUTPUT CIRCUITRY
28
PRESSURE SENSE
30
ECG SENSE AMP
32
34
36
40
HEART

Figure 1

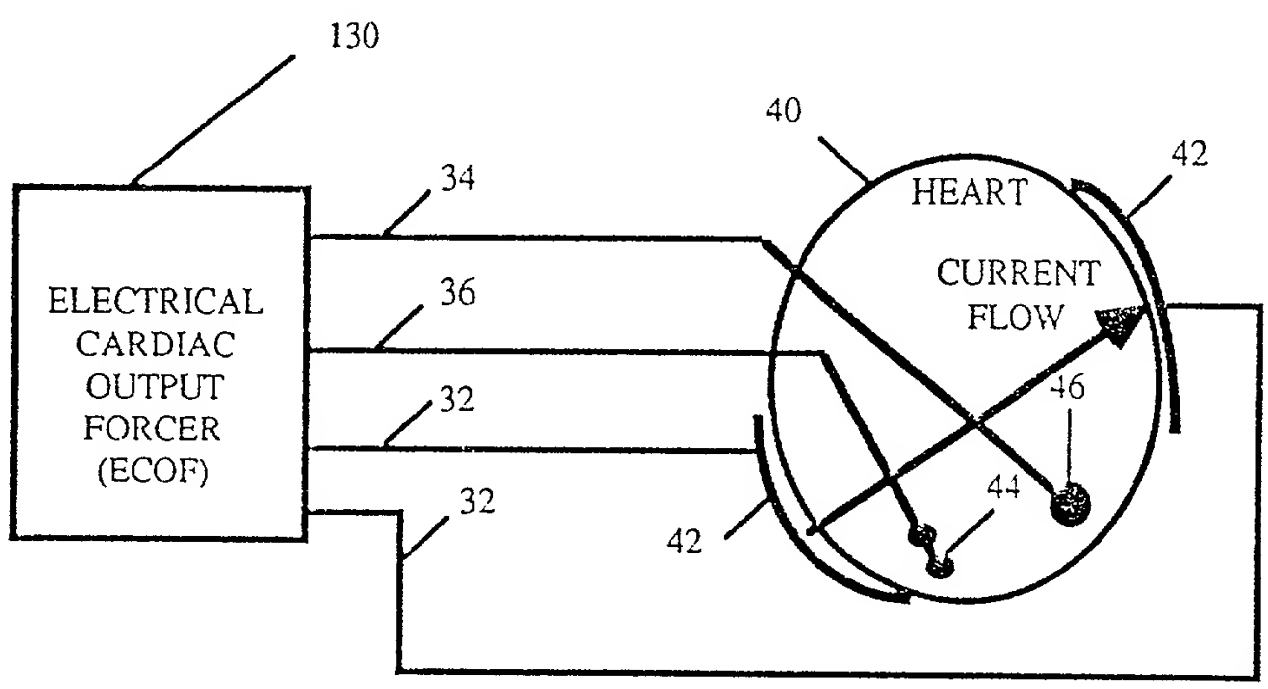
130
40
42
34
HEART
CURRENT
FLOW
36
ELECTRICAL
CARDIAC
OUTPUT
FORCER
(ECOF)
32
46
32
44
42

Figure 2a

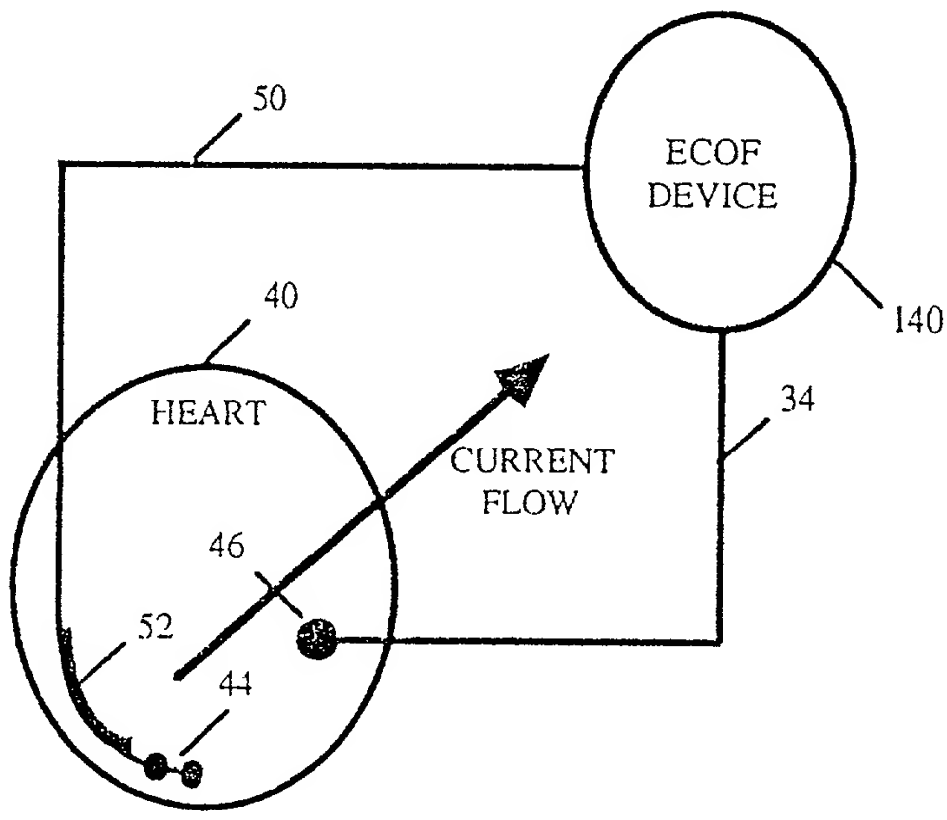

Figure 2b

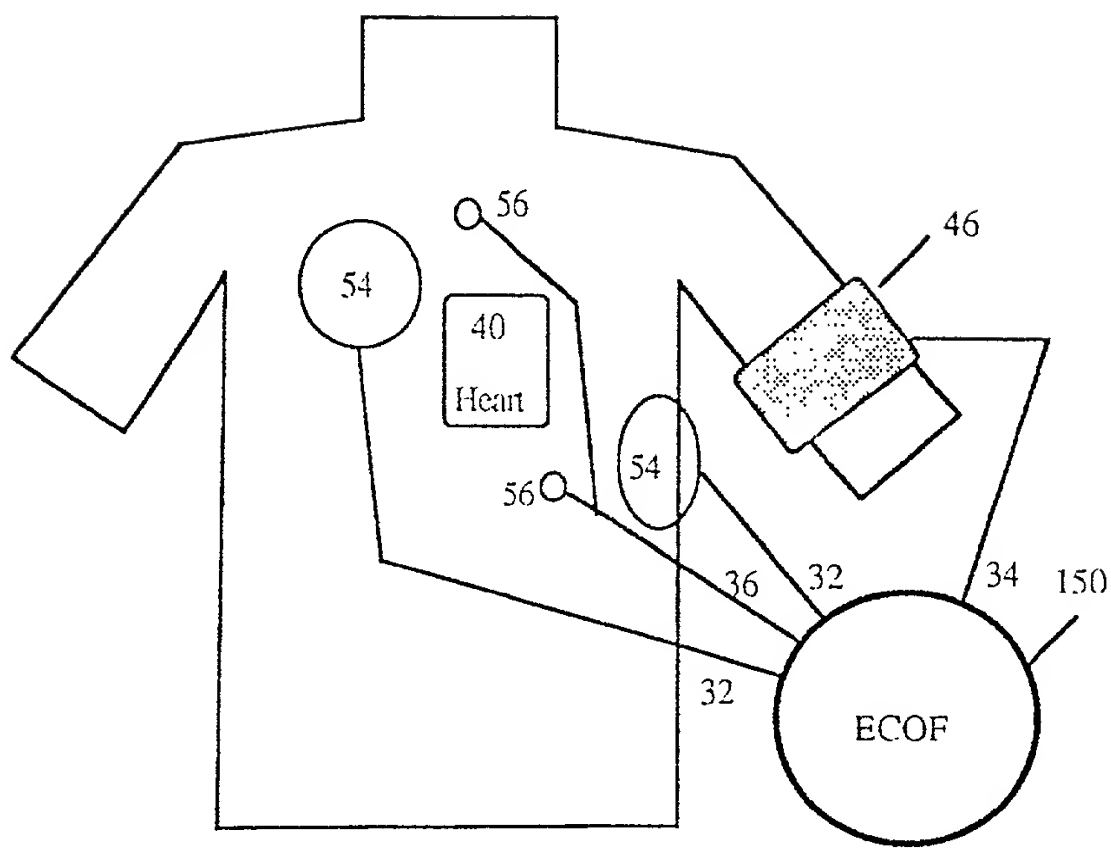

Figure 3

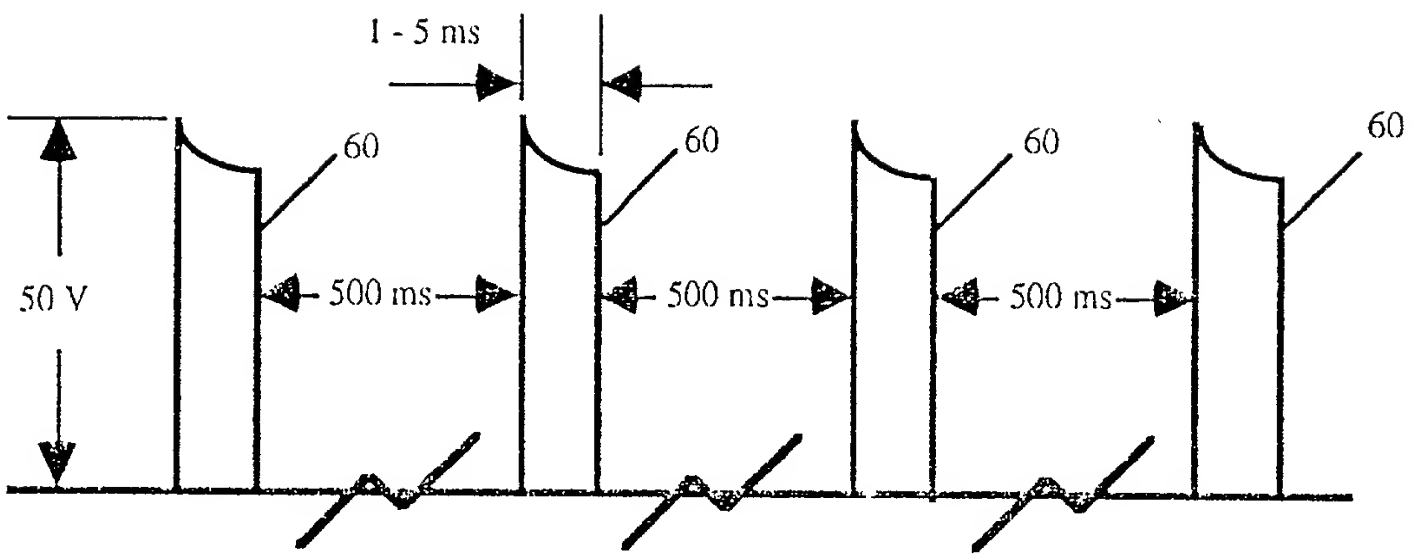

Figure 4

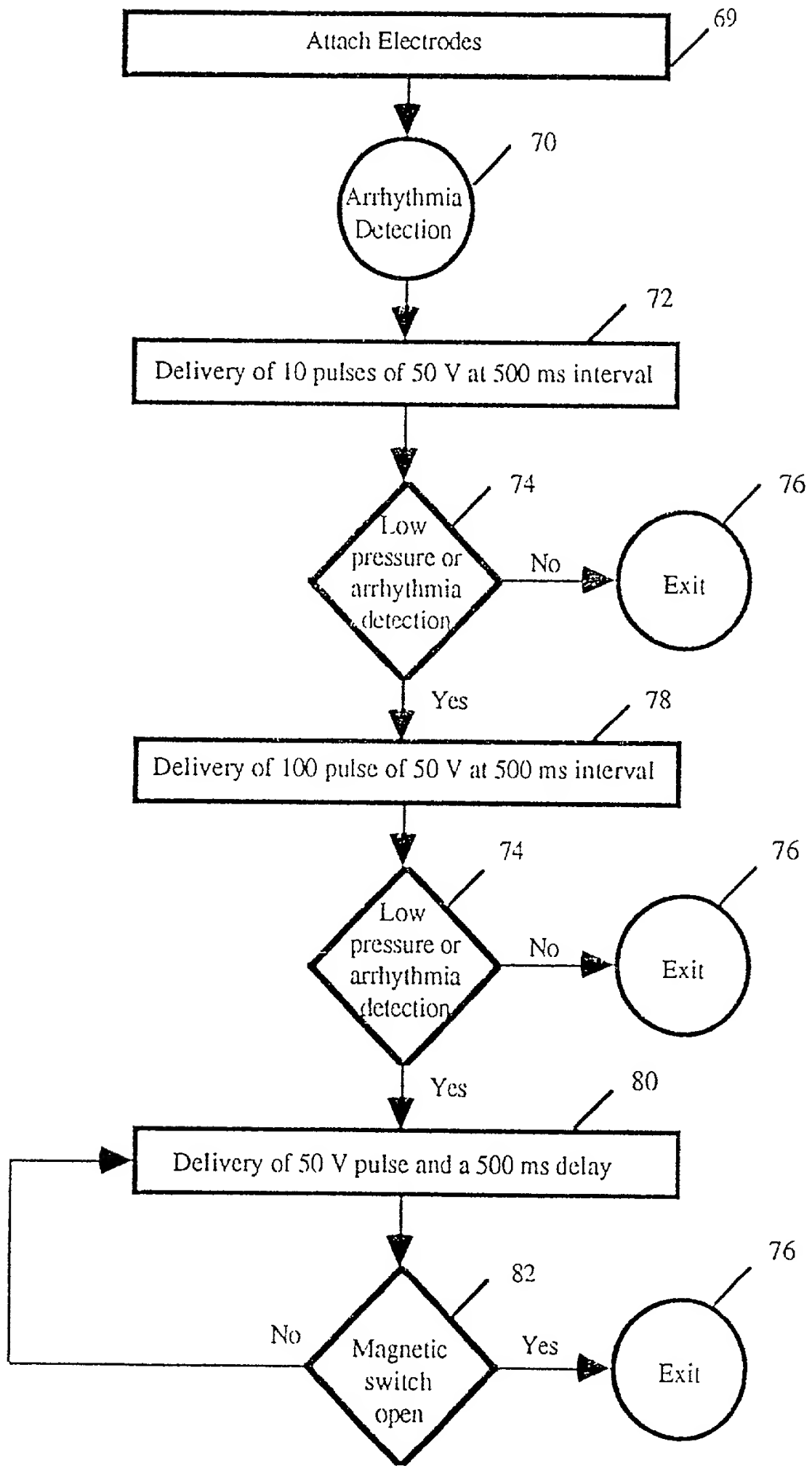
Attach Electrodes
69
Arrhythmia Detection
70
Delivery of 10 pulses of 50 V at 500 ms interval
72
Low pressure or arrhythmia detection
74
No
Exit
76
Yes
Delivery of 100 pulse of 50 V at 500 ms interval
78
Low pressure or arrhythmia detection
74
No
Exit
76
Yes
Delivery of 50 V pulse and a 500 ms delay
80
Magnetic switch open
82
No
Yes
Exit
76

Figure 5

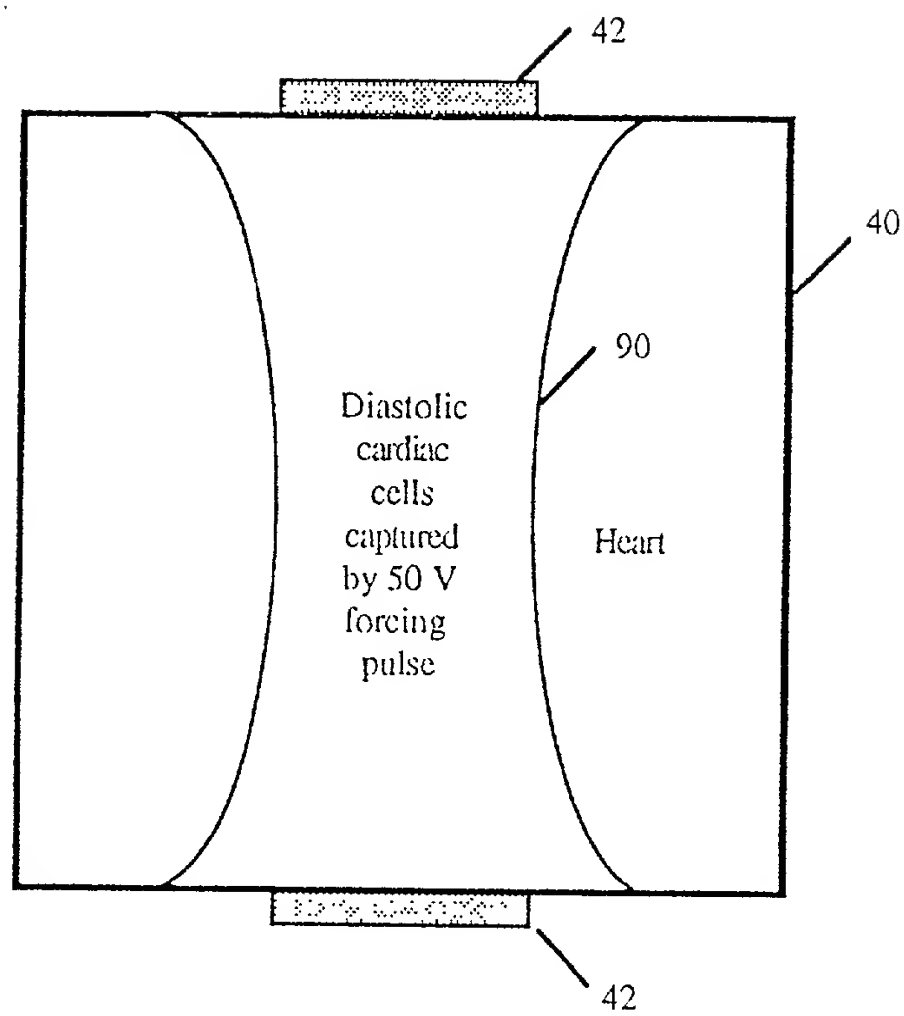
42
40
90
Diastolic
cardiac
cells
captured
by 50 V
forcing
pulse
Heart
42

Figure 6

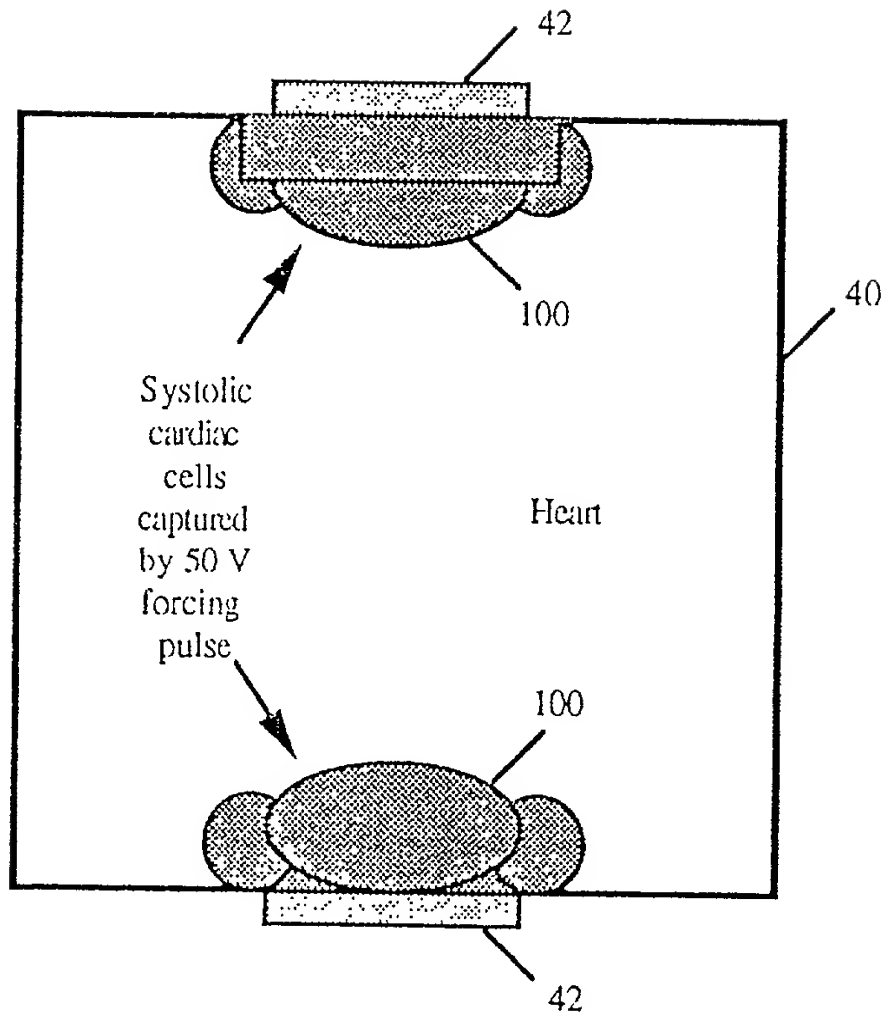
42
100
40
Systolic
cardiac
cells
captured
by 50 V
forcing
pulse
Heart
100
42

Figure 7

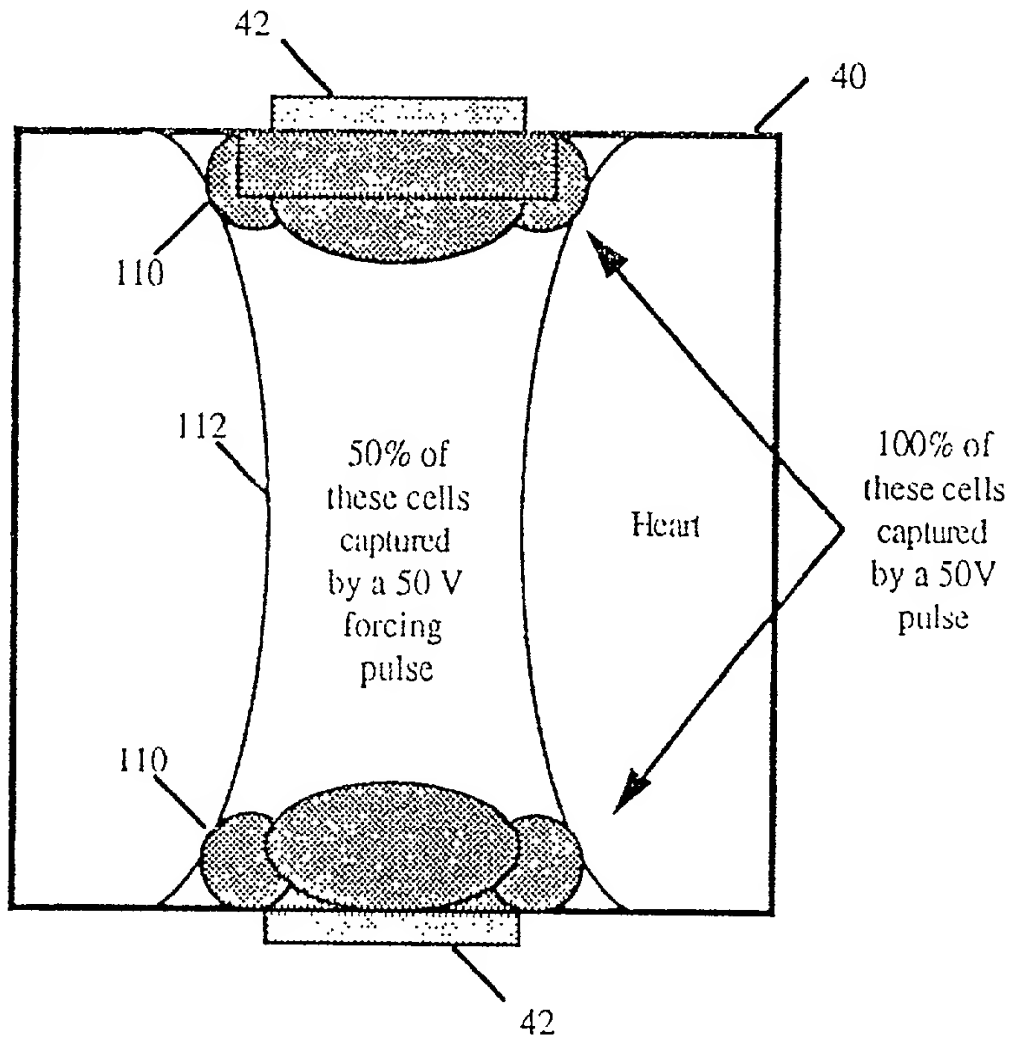
42
40
110
112
50% of these cells captured by a 50 V forcing pulse
Heart
100% of these cells captured by a 50V pulse
110
42

Figure 8

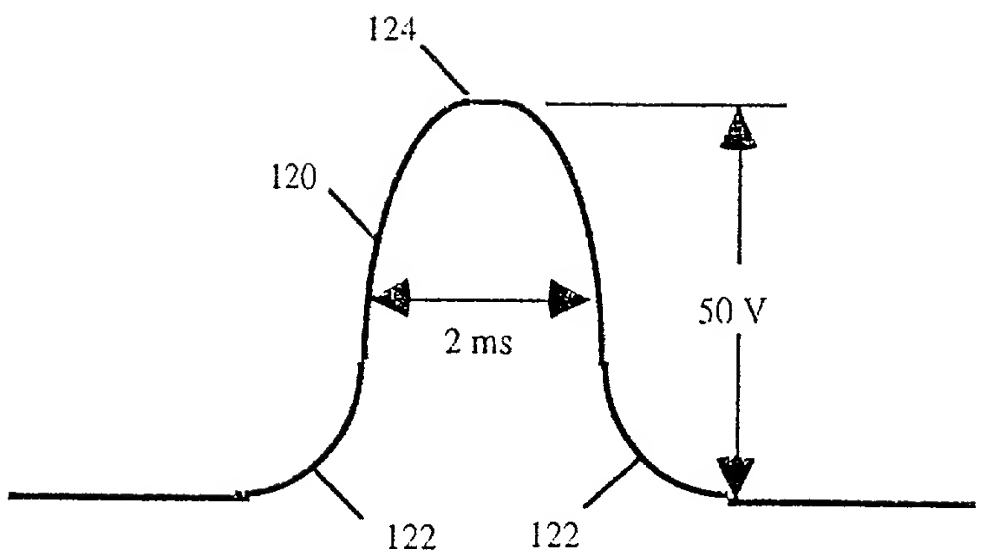

Figure 9a

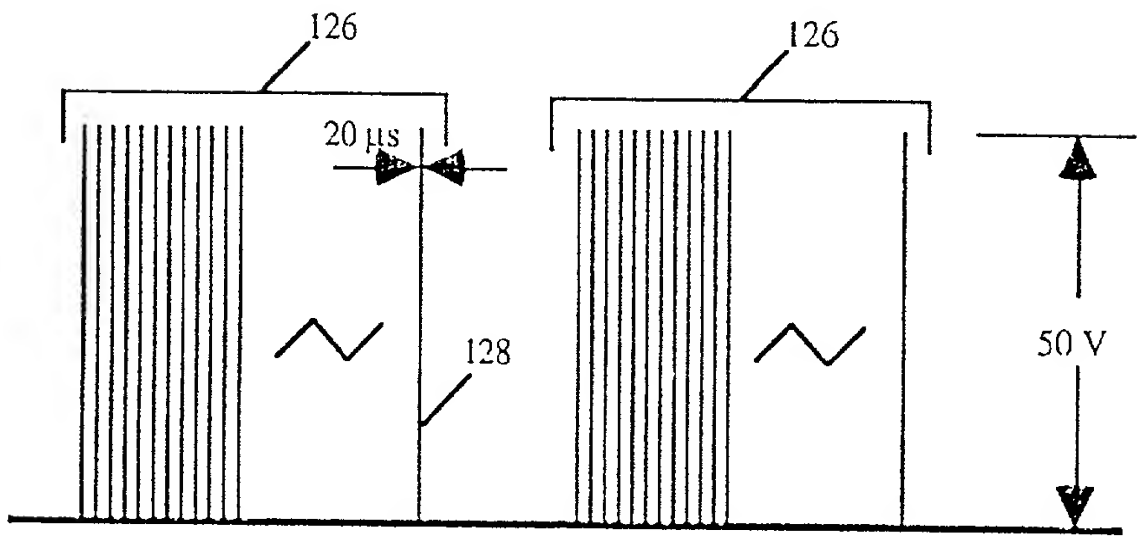

Figure 9b

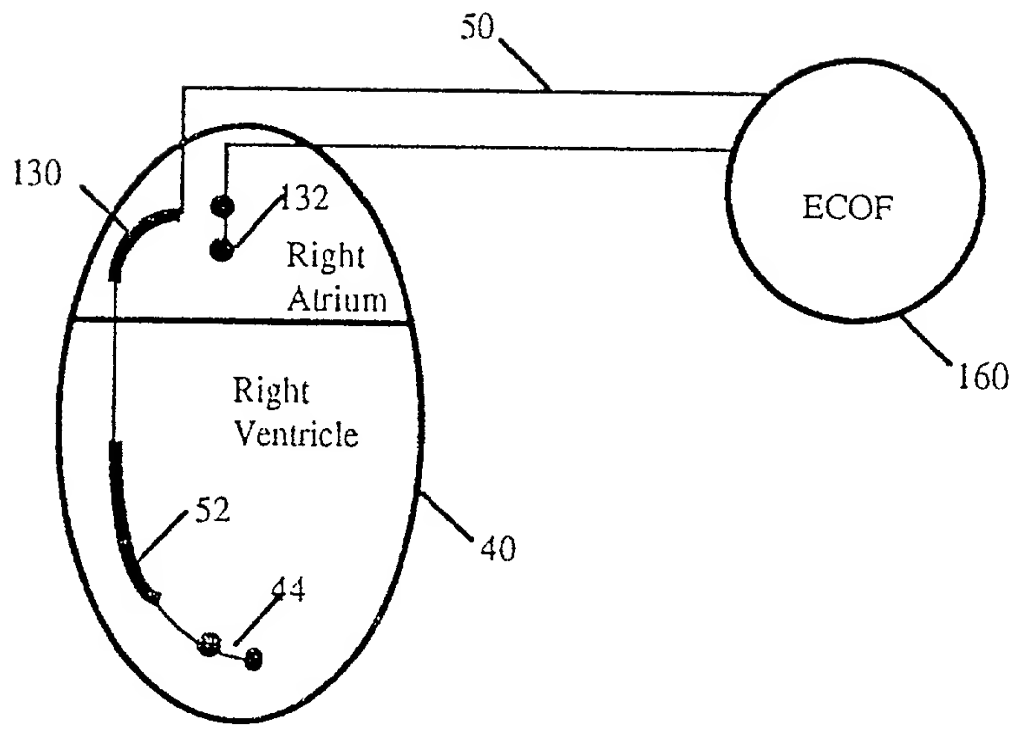

Figure 10

DECLARATION FOR PATENT APPLICATION

Docket Number (Optional)
KRO100CON

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled METHOD AND APPARATUS FOR TEMPORARILY ELECTRICALLY FORCING CARDIAC OUTPUT IN A TACHYARRHYTHYMIA PATIENT (AS AMENDED) the specification of which is attached hereto unless the following box is checked.

[X] was filed on 5/31/94 as United States Application Number or PCT International Application Number 08/251,349 and was amended on 6/12/95 (if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed

Prior Foreign Application(s) (Number)	(Country)	(Day/Month/Year Filed)	Priority Claimed
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

(Application Number)	(Filing Date)	(Status -- patented, pending, abandoned)
08/251,349	5/31/94	pending, to be abandoned

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

Joel D. Skinner, Jr. Reg. #33,786

Address all telephone calls to Joel Skinner at telephone number (715)386-5800

Address all correspondence to Joel D. Skinner, Jr.
619 Second Street, Suite 201
Hudson, WI 54016

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon

Full name of sole or first inventor (given name, family name) Kai Kroll

Inventor's signature [signature] Date 10/2/95

Residence Minnetonka, Minnesota USA Citizenship United States

Post Office Address 5217 W. Mill Road
Minnetonka, MN 55345

Full name of second joint inventor, if any (given name, family name) Mark W. Kroll

Second Inventor's signature _____ Date _____

Residence Minnetonka, MN 55345 Citizenship United States

Post Office Address 13011 Brenwood Trail
Minnetonka, MN 55345

☐ Additional inventors are being named on separately numbered sheets attached hereto.

DECLARATION FOR PATENT APPLICATION

Docket Number (Optional)
KR0100CON

As a below named inventor, I hereby declare that

My residence, post office address and citizenship are as stated below next to my name

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled METHOD AND APPARATUS FOR TEMPORARILY ELECTRICALLY FORCING CARDIAC OUTPUT IN A TACHYARRHYTHYMIA PATIENT (AS AMENDED) the specification of which is attached hereto unless the following box is checked

[X] was filed on 5/31/94 as United States Application Number or PCT International Application Number 08/251,349 and was amended on 6/12/95 (if applicable)

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Prior Foreign Application(s)			Priority Claimed
(Number)	(Country)	(Day/Month/Year Filed)	[ ] Yes [ ] No
(Number)	(Country)	(Day/Month/Year Filed)	[ ] Yes [ ] No
(Number)	(Country)	(Day/Month/Year Filed)	[ ] Yes [ ] No

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08/251,349 (Application Number)	5/31/94 (Filing Date)	pending, to be abandoned (Status - patented, pending, abandoned)
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Full name of sole or first inventor (given name, family name) Kai Kroll

Inventor's signature _____ Date _____

Residence Minnetonka, Minnesota USA Citizenship United States

Post Office Address 5217 W. Mill Road
Minnetonka, MN 55345

Full name of second joint inventor, if any (given name, family name) Mark W. Kroll

Second Inventor's signature [signature] Date 26 Sept 1995

Residence Minnetonka, MN 55345 Citizenship United States

Post Office Address 13011 Brenwood Trail
Minnetonka, MN 55345

[ ] Additional inventors are being named on separately numbered sheets attached hereto.